Remarks/Arguments

Claims 16, 20 – 24, and 27 – 28 remain in this application. Claims 17 – 19, 25 – 26, and 29 – 30 have been canceled.

Claim 16, as amended, discloses a method for the administration of therapeutic amount of a growth factor protein formulation in the treatment of a patient displaying the symptoms of acute coronary artery disease comprising the steps of: (a) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, PIGF, and mixtures thereof by inhalation therapy; (b) monitoring one or more clinical indicators of acute coronary artery disease; (c) determining, based on monitoring the one or more clinical indicators of acute coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary; (d) depending on the results of step c), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF1, FGF-2, PIGF, and mixtures thereof; and (e) repeating steps b) through d) until there is a clinical indication of amelioration of the symptoms of acute coronary artery disease in the patient, or until there is a contraindication to continued treatment.

Claim 24, as amended, recites substantially the same limitations as present claim 16, except that present claim 24 discloses a method for use in the treatment of chronic coronary artery disease, as opposed to acute coronary artery disease.

Claims 16, 20-24, and 27-28 were rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 11-15 and 20 of U.S. Patent No. 6,759,386 (6 July 2004) Franco. The Examiner has argued a statutory type double patenting rejection.

MPEP 804(II)(A) states the rules for determining whether a statutory double patenting rejection is appropriate. This section asks the question, "Is there an embodiment of the invention that falls within the scope of one claim, but not the other?" If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine." *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Present claims 16, 20 – 24, and 27 – 28 call for the method step of administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF-1, FGF-2, PIGF, and mixtures thereof by inhalation therapy. By way of

comparison, the '386 patent claims the method step of administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof by inhalation therapy. The '386 patent discloses at Col. 6, lines 53-56 that "[t]he VEGF family of structurally related growth factors has five mammalian members, VEGF, VEGF-B, VEGF-C, VEGF-D, and placenta growth factor (PIGF), all encoded by separate genes". The '386 patent further discloses at Col. 11, lines 4-8 that "using delivery and formulation technology available today, as would be recognized by one of skill in the appropriate art, it will be possible to deliver an effective amount of FGF and/or VEGF, and related growth factor proteins, in the treatment of chronic and acute heart disease."

Applicant respectfully submits that the same invention is not being claimed twice. Significantly, present claims 16, 20 – 24, and 27 – 28 call for a more narrowly defined combination of growth factors than those claimed in the '386 patent, because VEGF defines a broad family of growth factors, wherein PIGF is a specific member of that family. Therefore, it is respectfully submitted that identical subject matter is not defined by both sets of claims, respectively, and statutory double patenting does not exist.

Accordingly, reconsideration of the rejection of claims 16, 20 – 24, and 27 – 28 under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4, 5, 11, 12, 13, 14, 15, and 20 of the '386 patent is respectfully requested.

Conclusion

In view of the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Entry of this amendment, reconsideration of the rejection, and allowance of present claims 16, 20 – 24, and 27 – 28 are earnestly solicited.

Respectfully submitted,

Wayne P. Franco

By: _____

Ernest D. Buff
(His Attorney)
Reg. No. 25,833
(908-901-0220)